Remarks

Claims 1-24, and 32-38 are presented for the Examiner's review and consideration. In this response, claims 1-4, 6-7, 13, 15-17, 20-22, and 24 are amended; claims 25-31 are cancelled, and claims 32-38 are new. Applicant believes the accompanying remarks herein serve to clarify the present invention and are independent of patentability.

In a Final Office Action mailed January 30, 2007, claims 1-31 were rejected under 35 U.S.C. §102(e) as being anticipated by McDowell (6,171,340) ("McDowell"), and separately, Engh et al. (6,482,209) ("Engh").

In a reply filed March 30, 2007, Applicant submitted an affidavit with respect to Engh, pursuant to 37 C.F.R. §1.131. Applicant additionally submitted arguments directed to McDowell.

Interview Summary

Applicant and Applicant's attorney, Paul Bianco, appreciate the courtesies extended to them during a telephonic interview with Examiner Philogene on April 10, 2007. Applicant summarized the written arguments filed in response to the Office Action mailed January 30, 2007. In response, the Examiner stated that he would reconsider Applicant's written arguments.

In a subsequent advisory action mailed April 12, 2007, Applicant was advised that the reply failed to place the application in condition for allowance. In addition, Applicant's attention was directed to two additional references, Bouvet (French patent FR2682287) ("Bouvet") and Minfelde (French patent FR2768329) ("Minfelde").

McDowell

With reference to Figs. 5 and 6 of McDowell, a shield is implanted in a large hinge joint. (Col. 4, lns. 66-67). Troughs 34, 35 extend around the articulating surface of the condyles of the femur 50 and cup the condyles. (Col. 5, lns. 8-10). Preferably, troughs 34, 35 are interconnected, for example, an anterior bridge and posterior bridge 47 positioned between the troughs to preserve their proper alignment within the joint. (Col. 5, lns. 11-14).

Thus, McDowell discloses an implant having condylar regions connected by a bridge. The bridge is not disclosed as being formed by the surgeon either before or after implantation. Moreover, the bridge appears to have been formed to be integral with the condylar regions, during the manufacturing process, as if by casting or molding. Thus, the two portions appear to be parts of a whole, and formed as such prior to the time when the implant would arrive in a surgical theatre.

In contrast, with reference to Fig. 40 of the present invention, the femoral component 290 of an implant is formed as two separate portions 572 and 574. (¶[0364]). The portion 572 of the implant 290 is moved through the incision 114 into engagement with the distal end portion 124 of the femur 126. (Id). Thereafter, the portion 574 of the implant 290 is moved through the incision 114 into engagement with the distal end portion 124 of the femur 126. (Id). After the two portions 572 and 574 of the femoral component 290 of the implant have been positioned in abutting engagement with the femur 126, the two portions of the implant are interconnected at a joint 576 between the two portions of the implant. (Id).

The specific implant 290 illustrated in Fig. 40 has portions formed of a polymeric material which may be either a polymer or a co-polymer. (¶[0364]). The material of the two portions 572 and 574 of the implant 290 are heated at the joint 576 while the two portions of the implant are disposed in the patient's body in engagement with the femur 126. (Id). As this occurs, the material forming the two portions 572 and 574 of the implant 290 is heated to a temperature within its transition temperature range and becomes tacky without changing its overall configuration. (Id). The two portions 572 and 574 of the implant 290 may be heated by the direct or indirect application of heat. (Id). The indirect application of heat may include applying ultrasonic energy to the implant. (Id). With reference to Fig. 74A and B of the present invention, the portions may be bonded together by the application of energy in any one of many different forms, such as ultrasonic energy and heat. (¶[0636]). Alternatively, a snap type joint 576 could be provided between the portions 572 and 574 of the implant. (¶[0369]).

One of the features of the present invention relates to the making of a limited incision. (¶[0010]). The limited incision may be in any desired portion of a patient's body. (Id). For example, the limited incision may be in a knee portion of a leg of a patient. (Id). The limited incision may be made while the lower portion of the leg of the patient is suspended from the upper portion of the leg or while the lower portion of the leg and/or the foot of the patient are held by a support device. (Id).

As such, the present invention discloses implantable portions passed one after the other into the body, and thereafter interconnected. An energy source, such as ultrasound, bonds the portions where they are joined within the body. Additionally, this procedure may be performed while the leg is suspended.

As noted above, McDowell fails to disclose implantable portions connected inside the body, forming the connection with an energy source, or implantation while a leg is suspended. McDowell further fails to disclose a snap type joint between separate implant portions, and implantation in a context of minimally invasive surgery.

Claim 1 recites, *inter alia*, a modular joint implant implantable within a body through an opening in skin comprising: a plurality of separate implant portions each having an abutting surface including polymeric material, interconnectable and affixable together after passing separately through the skin, by the application of an energy source, to form a unitary implant having an articulating surface, wherein the plurality of separate implant portions are affixable to at least one joint member of a joint.

Claim 13 recites, *inter alia*, a modular joint implant implantable within a body through an opening in skin, comprising: a plurality of separate implant portions affixable together after passing separately through the skin to form a unitary implant having an articulating surface comprising at least separate medial and lateral implant portions, wherein the plurality of separate implant portions are affixable to at least one joint member of a knee joint.

Claim 21 recites, *inter alia*, a modular femoral joint implant implantable within a body comprising: first and second implant portions bondable together within the body to form a unitary implant and affixable to a femoral joint member of a knee joint,

wherein said first and second implant portions are implanted while the lower portion of the leg of the patient is suspended from the upper portion of the leg.

Claim 22 recites, *inter alia,* a method of replacing a portion of a joint, in a body, with a modular joint implant, comprising the steps of: providing the modular joint implant as a plurality of separate implant portions interconnectable and affixable together in the body to form a unitary implant having an articulating surface; preparing the joint member to receive the modular joint implant; sequentially positioning the plurality of separate implant portions on the prepared joint member; and affixing the separate implant portions together by means of either ultrasonic energy or a mechanical fastener.

Accordingly, Applicant respectfully submits that claims 1, 13, 21, and 22 are patentable over McDowell. As claims 2-12 depend from claim 1, 14-20 from claim 13, and 23-24 from claim 22, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are patentable over McDowell for the same reasons.

Bouvet

Bouvet was cited in a previous Office Action, and a translation was provided by the Applicant in a response filed November 20, 2006. This discussion will reference the translation therein provided.

With reference to the figures of Bouvet, the two condylar surfaces 8, 9 are obviously separated, but are joined to each other by a bridge 15 that has an arch shape, situated in the space delimited by the concave face 25 of the condylar surfaces 8, 9. (¶15). For the trochlea 11 to be constructed of a different material 23 from that 21 of the condylar surfaces, it is advantageous to fabricate these two elements in two separate parts... (¶16). In the interest of secureness, however, and to facilitate its implantation, the trochlea 11 further comprises a tab 29 designed to be inserted between the two condylar surface 8, 9 and beneath the arch of bridge 15. (¶17). In addition, the fact that the trochlea 11 is disassociated from the condylar surfaces 8, 9 makes it possible for the stresses applied at the level of the condylar surfaces not to be transmitted to the trochlea, and vice versa. (¶20).

As such, Bouvet discloses a knee implant having a condylar part representing both condyles, and a trochlear part, that are not interconnected; rather, they are independently connected to the femur, and are specifically disassociated, in order to provide different stress levels to each part.

Thus Bouvet does not show a modular joint implant that is interconnectable and affixable together. Moreover, Bouvet does not disclose an interconnection through the use of an energy source, implantation while the leg is suspended, separate medial and lateral portions of an implant, implantation while a leg is suspended, connecting portions by snap fastening, or implantation in a context of minimally invasive surgery.

Minfelde

Minfelde discloses a knee joint prosthesis having a femoral component made from an anterior trochlea section 18 and posterior condyle 17 section with convex outer surfaces, joined together by sliding couplings running in an anterior-posterior direction, enabling their relative positions to be adjusted in that direction and fixed by locking elements 19. (Abstract) The sliding couplings are in the form of tenon and mortise joints, with the trochlea and condyle sections designed so that their central condyle articulation surfaces are continuous regardless of their relative positions. (Id).

With reference to the figures of Minfelde, it can be seen that the disclosed implant is formed in two parts, a trochlea part 18, and a condylar part containing both condyles 17. The parts are joined along an anterior posterior axis.

Thus, Minfelde does not disclose a medial/lateral connection, or two separate condylar sections connected within the body. Minfelde further does not disclose affixing separate implant portions through the application of energy applied to polymeric material, implantation while a leg is suspended, connecting portions by snap fastening, or implantation in a context of minimally invasive surgery.

Applicant appreciates this opportunity to address the cited references, and thus perhaps advance the prosecution of the application.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested.

If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of $790 for a Request for Continued Examination (RCE) is believed to be due. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 780-A03-012A).

Respectfully submitted,

Paul D. Bianco, Reg. # 43,500

Customer Number: 33771
FLEIT KAIN GIBBONS GUTMAN BONGINI & BIANCO P.L.
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: pbianco@focusonip.com